(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 July 2004 (22.07.2004)

PCT

(10) International Publication Number
WO 2004/060099 A2

(51) International Patent Classification[7]: A45C 11/00, 11/04, B65B 25/00

(21) International Application Number: PCT/US2003/039017

(22) International Filing Date: 9 December 2003 (09.12.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/436,109 23 December 2002 (23.12.2002) US

(71) Applicant: **JOHNSON & JOHNSON VISION CARE INC.** [US/US]; 7500 Centurion Parkway, Jacksonville, FL 32256 (US).

(72) Inventors: **PECK, James**; 13587 Osprey Point Drive, Jacksonville, FL 32224 (US). **DUBEY, Dharmesh**; 9087 Starpass Drive, Jacksonville, FL 32256 (US). **TOKARSKI, Michael**; 500 N. Lakewood Run, Ponte Vedra Beach, FL 32082 (US). **ZHANG, Qiang**; 27 LaCosta Drive, Annandale, NJ 08801 (US). **LI, Yufu**; 11 Hughes Road, Bridgewater, NJ 08807 (US). **ARNOLD, Steven**; 26 Hideaway Lane, Sparta, NJ 07871 (US).

(74) Agents: **JOHNSON, Philip S,** et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).

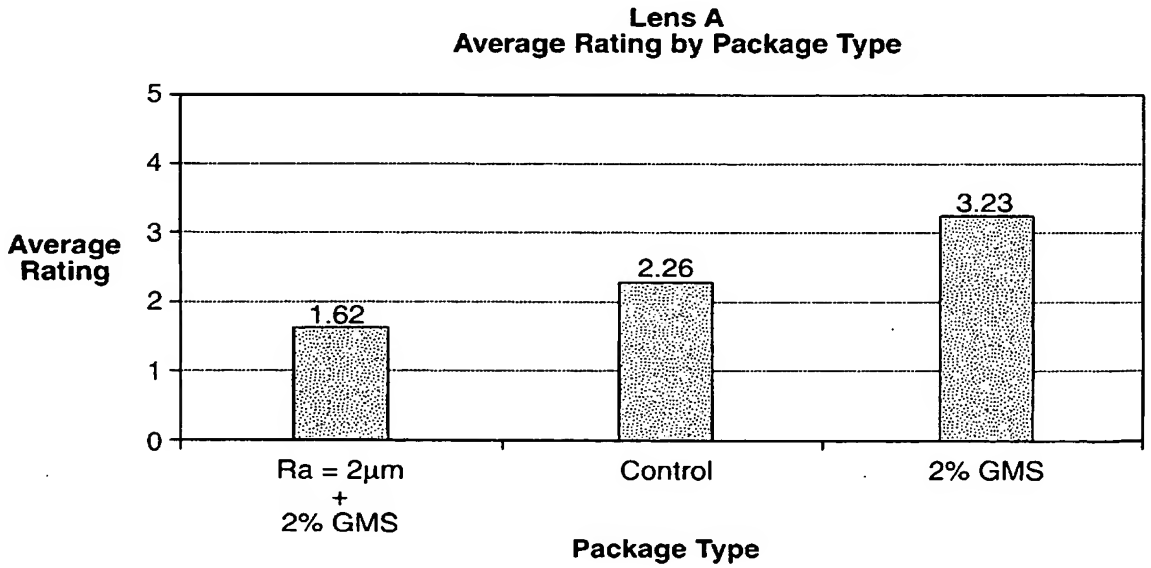
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CONTACT LENS PACKAGES CONTAINING ADDITIVES



(57) Abstract: A package having an additive that does not adhere to a medical device enclosed therein.

CONTACT LENS PACKAGES CONTAINING ADDITIVES

RELATED APPLICATIONS

This application is a non-provisional filing of a provisional application, U.S. Pat. App. No.60/436,109, filed on December 23, 2002.

FIELD OF THE INVENTION

This invention related to packages for storing contact lenses as well as methods of using and preparing these packages.

BACKGROUND

Contact lenses have been used commercially to improve vision since the 1950s. At first contact lenses were made of hard materials, which were relatively easy to handle and package for use, but were uncomfortable for many patients. Later developments, gave rise to softer more comfortable lenses made of hydrophobic hydrogels, particularly silicone hydrogels. These lenses are very pliable, but due to this texture and their chemical composition, they present a number of problems with packaging.

Most contact lenses are packaged in individual blister packages having a bowl portion and a foil top, where the bowl portion is made from a hydrophobic material such as polypropylene. *See* U.S. Patent Nos. 4,691,820; 5,054,610; 5,337,888; 5,375,698; 5,409,104; 5,467,868; 5,515,964; 5,609,246; 5,695,049; 5,697,495; 5,704,468; 5,711,416; 5,722,536; 5,573,108; 5,823,327; 5,704,468; 5,983,608; 6,029,808; 6,044,966; and 6,401,915 for examples of such packaging, all of which are hereby incorporated by reference in their entirety. While polypropylene is resilient enough to withstand the sterilization steps of contact lens manufacture, this material has an affinity for contact lenses made of silicone hydrogels. When silicone hydrogels are packaged in polypropylene bowls, the lenses stick to the bowl and cannot be removed from the package without damaging the pliable lenses. Therefore is a need to prepare a contact lens package that has resilient properties, but does not stick to the final product. It is this need that is met by the following invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates the data for Lens A in different packages

Figure 2 illustrates the data for Lens B in different packages

Figure 3 illustrates the data for Lens C in different packages

DETAILED DESCRIPTION OF THE INVENTION

This invention includes a package for storing medical devices in a solution comprising, consisting essentially of, or consisting of, a molded base wherein the molded base comprises an additive, provided that the medical device is not a contact lens consisting of acqualfilcon A coated with polyHema.

As used herein a "medical device" is any device that is stored or packaged in a solution and is used to treat a human disease. Examples of medical devices include but are not limited to ophthalmic devices that reside in or on the eye. Ophthalmic devices includes but are not limited to soft contact lenses, intraocular lenses, overlay lenses, ocular inserts, and optical inserts. These devices can provide optical correction or may be cosmetic. The preferred medical devices of the invention are soft contact lenses made from silicone elastomers or hydrogels, which include but are not limited to silicone hydrogels, and fluorohydrogels. Soft contact lens formulations are disclosed in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002, US Patent No. 5,710,302, WO 9421698, EP 406161, JP 2000016905, U.S. Pat. No. 5,998,498, US Pat. App. No. 09/532,943, U.S. Patent No. 6,087,415, U.S. Pat. No. 5,760,100, U.S. Pat. No.5,776, 999, U.S. Pat. No. 5,789,461, U.S. Pat. No. 5,849,811, and U.S. Pat. No. 5,965,631. The foregoing references are hereby incorporated by reference in their entirety. The particularly preferred medical devices of the invention are soft contact lenses made from etafilcon A, genfilcon A, lenefilcon A, polymacon, balafilcon A, lotrafilcon A. and silicone hydrogels as prepared in U.S. Pat. No. 5,998,498, U.S. Pat. App. No. 09/532,943, a continuation-in-part of US Pat App. No. 09/532,943, filed on August 30, 2000, U.S. Patent No. 6,087,415, U.S. Pat. No. 5,760,100, U.S. Pat. No.5,776, 999, U.S. Pat. No. 5,789,461, U.S. Pat. No. 5,849,811, and U.S. Pat. No. 5,965,631. These patents as well as all other patent disclosed in this application are hereby incorporated by reference in their entirety. The more particularly preferred medical devices of the invention are soft contact lenses, balafilcon A, lotrafilcon A, galyfilcon A, senofilcon A, or those made as

described in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002. The most particularly preferred medical devices are soft contact lenses made from either galyfilcon A or senofilcon A.

The term "molded base" refers to any polymer, rubber, or plastic that can be formed into a receptacle for medical devices, where the size and shape of the base are determined by the device and other considerations known those who are skilled in the art of making or designing molded bases. For example molded bases may be individual blister packages, secondary packages, or hydrating trays. The molded base may be prepared from any number of materials provided that those materials are compatible with the chemical and physical properties of the device. Examples of suitable materials include but are not limited to polypropylene, polyethylene, nylons, olefin co-polymers, acrylics, rubbers, urethanes, polycarbonates, or fluorocarbons. The preferred materials are metallocenes polymers and co-polymers made of polypropylene, polyethylene, having a melt flow range of about 15 g/10 minutes to about 44 g/10 minutes as determined by ASTM D-1238. With respect to the shape of the molded base, examples of suitably shaped bases are disclosed in the following patents which are hereby incorporated by reference in their entirety, U.S. Patent Nos. D 458,023; 4,691,820; 5,054,610; 5,337,888; 5,375,698; 5,409,104; 5,467,868; 5,515,964; 5,609,246; 5,695,049; 5,697,495; 5,704,468; 5,711,416; 5,722,536; 5,573,108; 5,823,327; 5,704,468; 5,983,608; 6,029,808; 6,044,966; and 6,401,915. As in the cited references, the molded based is sealed about the cavity that encloses the contact lens. Flexible cover sheets can be made from can be an adhesive laminate of an aluminum foil and a polypropylene film or any other extruded or co-extruded film that can be sealed to the top surface of the flange in order to form a hermetic seal for the medical device and the solution. Further, the base can be formed by any of a number of known methods which include but are not limited to injection molding, transfer molding, skin packaging, blow molding, coinjection molding, film extrusion, or film coextrusion.

As used herein the term "additive" refers to a substance that is added to the polymer, rubber, or plastic prior to forming the molded base, where the material inhibits sticking, adherence, or adhesion of the medical device to the molded base. The additive is mixed with the remainder of the molded base material and amount of additive present by weight percentage based on the total weight of the molded base material is greater than about 0.25 to about 10 weight percent, preferably greater than about 0.25 to about 5 weight percent, most preferably about 0.25 to about 3 weight percent. The preferred additives are glycerol monostearate (2%), polyvinylpyrolidone (1% to 5%), polyvinylpyrolidone/maleic anhydride (1/1% to 5/5%), and succinic acid (5%). Polyvinylpyrolidinone has a variety of molecular weight ranges (as indicated by the KD#) and consistencies (flake, powdered/micronized). When PVP KD90 is used as an additive, it is preferred that it is powered/micronized.

The term "solution" refers to any liquid medium in which a medical device is stored. The preferred solutions are aqueous solutions contain physiological buffers. The particularly preferred solution is saline solution.

For example, if the medical device is a contact lens, it is preferred that the molded base is transparent to the degree necessary to permit visual inspection, UV sterilization or both. The preferred additives are glycerol monostearate present at about 2 weight percent, succininc acid present at about 5 weight percent, PVP KD90 present at about 1-5 weight percent, PVP/maleic anhydride present at about 1/1 to about 5/5 weight percent. If the inner surface of the medical device has a roughness of about 0.2 μm to about 4.5 μm, the preferred additives are maleic anhydride or PVP/maleic anhydride, most preferably maleic anhydride.

Further, the invention includes a method of reducing the adherence of a medical device to its packaging, comprising, consisting essentially of, or consisting of, storing said medical device in a solution in a package comprising, consisting essentially of, or consisting of, a molded base wherein said molded base comprises an additive, provided that the medical device is not a contact lens consisting of acqualfilcon A coated with polyHema. The terms molded base, medical device, solution and additive all have their aforementioned meanings and preferred ranges.

When soft contact lenses are prepared, the lenses cured to a hard disc and subsequently hydrated with water to give the non-sterilized final product. During this hydration step, soft contact lenses often stick to the surface of the hydration chamber and it would useful to find a method of hydrating soft contact lenses which alleviates this problem.

To solve this problem, the invention includes a method of hydrating a contact lens comprising, consisting essentially of, or consisting of hydrating said lens in a molded base wherein said molded base comprises an additive. The terms molded base, medical device, solution and additive all have their aforementioned meanings. The preferred values for the medical device, the solution and the additive are as listed above. The preferred molded base is a square or a rectangle.

Other have tried to address the problem of a medical device adhering to its packaging. For example U.S. Pat App. No. 09/942,347, entitled "Textured Contact Lens Package," filed on August 29, 2001 and U.S. Pat. App. No. 10/183,133, entitled "Contact Lens Packages,"filed on June 26, 2002 disclose solutions to this problem. The disclosure of these applications are hereby incorporated by reference in their entirety. Even though those methods address this problem, it is contemplated by the inventors of this patent application that the additives of this invention may be incorporated into the packaging of each of the cited references.

In order to illustrate the invention the following examples are included. These examples do not limit the invention. They are meant only to suggest a method of practicing the invention. Those knowledgeable in contact lenses as well as other specialties may find other methods of practicing the invention. However, those methods are deemed to be within the scope of this invention.

EXAMPLES

The following abbreviations are used below

Ampacet 40604	fatty acid amide
ATOFINA 3924CWZ	Finacene Nucleated polypropylene having a melt flow of 55g/10 minutes, ASTM D1238. This material contains an antistat and a lubricant
Atmer 163	fatty alkyl diethanolamine Reg. No.107043-84-5

Dow Siloxane MB50-321	a silicone dispersion
Epolene E43-Wax,	maleic anhydride produced by Eastman Chemical
Erucamide	fatty acid amide Registry No. 112-84-5
Exxon 1605	Exxon Achieve, PP1605, a metallocene polypropylene having a melt flow of 32 g/10 minutes, ASTM D-1238 (L)
Exxon 1654	Exxon Achieve, PP1654, a metallocene isotactic polypropylene having a melt flow of 16 g/10 minutes, ASTM D-1238 (L)
Fina EOD-001	Finacene, a metallocene and isotactic polypropylene having a melt flow of 16g/10 minutes, ASTM D1238
Flura	Registry No.7681-49-4
Kemamide	fatty acid amide
Licowax	fatty acid amide
Mica	Registry No. 12001-26-2
Nurcrel 535 & 932	ethylene-methacrylic acid co-polymer resin Registry No. 25053-53-6
Oleamide	fatty acid amide Registry No. 301-02-0
polyHema	poly hydroxy ethylmethacylate having a molecular weight of greater than 1MM Dalton
mPDMS	800-1000 MW monomethacryloxypropyl terminated polydimethylsiloxane
Pluronic	polyoxypropylene-polyoxyethylene block co-polymer Registry No.106392-12-5
PVP	poly vinyl pyrrolidinone, wherein KD# refers to different known molecular weight distributions of poly vinyl pyrrolidinone
Simma 2	3-methacryloxy-2-hydroxypropyloxy)propylbis (trimethylsiloxy)methylsilane
Super-Floss anti block	slip/anti blocking agent, Registry No. 61790-53-2
Tetronic	alkyoxylated amine 110617-70-4
Zeospheres anti-block	slip/anti blocking agent

Lens Preparations

Lens A	Acquafilcon A lenses coated with polyhema having a molecular weight of about 1,000,000. *See* U.S. Pat App. No. 09/957,299, entitled "Soft Contact Lenses," filed on September 20, 2001, Example 27. The coating method is disclosed in U.S. Pat. App. No. 09/921,192, entitled "Method for Correcting Articles by Mold Transfer," filed on August 2, 2001.
Lens B	Contact lenses prepared as described in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002, containing by weight percent 30% Simma 2, 19% mPDMS, 31% DMA, 6% PVP (MW 360,000), 0.8%EDGMA, 0.23% CGI81, 1.5% Norbloc, 11% PVP (MW 2,500), 0.02% Blue Hema, 0-2 ac PDMS, 29% t-amyl alcohol.
Lens C	Contact lenses prepared as described in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002, containing by weight percent 28% Simma 2, 31% mPDMS, 23.5% DMA, 7% PVP (MW 360,000), 1.5%TEDGMA, 0.98% CGI 1850, 2.0% Norbloc, 6 HEMA, 0.02% Blue Hema.

Example 1

Preparation of Packages with Different Additives

Additives (identity and amounts listed in Table 1) were mixed with polypropylene (listed below). The material was injection molded to form the base portion of a contact lens package. The configuration of the package is as

illustrated in Figure1 of U.S. Pat No. 5,467,868 which is hereby incorporated by reference.

Contact lenses made from acquafilcon A coated with polyhema, a silicone hydrogel, were added to individual polypropylene blister packs having different additives containing 950μL of saline solution and then the blister pack was heat sealed with an flexible cover. Lenses were visually evaluated for adhesion to the package after sterilization. The flexible cover sheet was removed and the molded base is rotated or jiggled without spilling the saline solution while a contact lens is observed to determine if it is adhered to the inner surface of the molded base. Lenses that do not adhere are free floating and pass the test. If the lenses adhere to the molded base in any manner they fail the test. The addtitive, its weight percentage, the number of lenses that stuck to the package, and number of lenses that were free floating are displayed in Table 1. This example illustrates that glycerol monostearate is a superior additive.

TABLE 1

Polypropylene	Additive	# tested	# stuck
Exxon 1605	none	12	12
Exxon 1605	calcium stearate	36	36
Exxon 1605	2% glycerol monostearate	36	3
Exxon 1654	2% glycerol monostearate	84	2
Exxon 1654	none	12	12
Exxon Exxelor P1020	none	12	12
Fina EOD-0011	none	12	12
Fina EOD-0011	1% zinc stearate	12	12
Fina EOD-0011	3% zinc stearate	12	12
FINA 3924CW@	antistat	36	36

Example 2

Consumer Test

Packages containing 2% weight percent GMS and Exxon 1605 were prepared using the method of Example 1. Contact lenses of types A, B, and C

were added to individual blister packages along with 950 μL of saline solution. The filed packages were heat sealed with flexible covers and sterilized. The packaged lenses were submitted to consumers. The consumers opened the packages and evaluated the lenses for ease of removal of the lens from the package using the following criteria and grading system

1-very easy removal-Lens comes out without any problems

2-easy removal-a couple of attempts to remove the lenses, but overall there were no real problems in removal

3-moderate removal- several tries before lens comes out, neither pleased or displeased

4-difficult removal-many tries to remove with finger or nail-removal is frustrating

5-very difficult removal-many tries to remove with a finger or nail, lens damage upon removal- very unacceptable

Figure 1 illustrates the testing results for a comparison of Lens A in a polypropylene package (control), Lens A in a package containing 2.0% GMS where the package has an average surface roughness (Ra) of about 2.0 μm, and Len A in a package containing 2.0% GMS. This figure shows that the roughened package containing GMS has the highest consumer rating.

Figure 2 illustrates the testing results for a comparison of Lens B in a polypropylene package (control), Lens B in a package containing 2.0% GMS where the package has an average surface roughness (Ra) of about 2.0 μm, and Len B in a package containing 2.0% GMS. This figure shows that the package containing 2.0 %GMS has the highest consumer rating.

Figure 3 illustrates the testing results for a comparison of Lens C in a polypropylene package (control), Lens C in a package containing 2.0% GMS where the package has an average surface roughness (Ra) of about 2.0 μm, and Len C in a package containing 2.% GMS. This figure shows that the package containing 2.0 %GMS has the highest consumer rating.

Example 3

Preparation of Packages With Different Additives

The testing methods and preparations of Example 1 were repeated with different additives and lens types as per Table 2. If "(UP)" appears in an entry, that bowl of the blister is shaped as in U.S. Pat. No. D 458,023. When the term "Rough Bowl" appears, the inside surface of the bowl is roughened to an Ra of 0.5mm to 0.8mm.

Table 2

Base Resin	Lens Type	Tested	Stuck	Additive
Exxon 1605 PP	Lens B	15	13	Calcium stearate (2%)
Exxon 1605 PP	Lens B	120	0	GMS (2%)
Exxon 1605 PP	Lens C	30	0	GMS (2%)
Exxon 1605 PP	Lens B	15	12	Dow Siloxane MB50-321 (10%)
Exxon 1605 PP	Lens B	15	13	Dow Siloxane MB50-321 (5%)
Exxon 1605 PP	Lens B	57	50	Ampacet 40604 99.5/.5 Erucamide
Ampacet 40604 PP	Lens B	15	15	Erucamide (5%)
Exxon 1605 PP	Lens B	15	15	Kemamide (Erucamide) (5%)
Exxon 1605 PP	Lens B	15	12	Superfloss anti-bock (2%)
Exxon 1605 PP	Lens B	15	15	Zeospheres anti-block (2%)
Exxon 1605 PP	Lens B	15	14	Superfloss anti-bock (2%) Oleamide (.2%)
Exxon 1605 PP	Lens B	14	13	Superfloss anti-bock (.2%) Oleamide (.2%)
Exxon 1605 PP	Lens B	15	15	Talc (5%)
Exxon 1605 PP	Lens B	15	13	Calcium carbonate (5%)
Exxon 1605 PP	Lens B	15	14	Zinc stearate (5% hand blend)
Exxon 1605 PP	Lens B	15	15	Zinc stearate (5% machine blend)
Exxon 1605 PP	Lens B	15	14	ATP (Vitamin E) (5%)
Exxon 1605 PP	Lens B	15	13	Licowax (1%)
Exxon 1605 PP	Lens B	15	14	Polyethyleneglycol monolaurate (5%)
Exxon 1605 PP	Lens B	15	15	Mica (5%)
Exxon 1605 PP	Lens B	175	8	Succinic Acid (5%)
Exxon 1605 PP	Lens B	15	13	Succinic Anhydride (5%)
Exxon 1605 PP	Lens B	118	22	Epolene E-43 (20% machine blend)
Exxon 1605 PP	Lens B	100	92	Epolene E-43 (20% machine blend)
Exxon 1605 PP	Lens B	127	52	Epolene E-43 (10% hand blend)
Exxon 1605 PP	Lens B	130	16	Epolene E-43 (10% machine blend)
Exxon 1605 PP	Lens C	15	6	Epolene E-43 (10% machine blend)
Exxon 1605 PP	Lens B	30	22	Epolene E-43 (5% machine blend)
Exxon 1605 PP	Lens C	15	3	Epolene E-43 (5% machine blend)
Exxon 1605 PP	Lens B	15	15	Atmer 163 (1%)
Exxon 1605 PP	Lens B	15	10	MC (5%)
Exxon 1605 PP	Lens B	30	2	Boric Acid (5% hand blend)
Exxon 1605 PP	Lens B	215	3	Boric Acid (5% machine blend)
Exxon 1605 PP	Lens C	15	0	Boric Acid (5% machine blend)
Exxon 1605 PP	Lens B	15	13	Boric Acid (3% hand blend)
Exxon 1605 PP	Lens B	15	15	Boric Acid (2% hand blend)
Exxon 1605 PP	Lens B	150	4	Epolene E-43 (10% machine blend)
Exxon 1605 PP	Lens B	50	9	Epolene E-43 (10% machine blend)
Exxon 1605 PP	Lens B	50	15	Epolene E-43 (10% machine blend)
Exxon 1605 PP	Lens B	50	35	Epolene E-43 (10% machine blend)
Exxon 1605 PP	Lens B	255	6	PVP K90 (5.0%)
Exxon 1605 PP	Lens B	98	31	PVP K90 (2.5%)
Exxon 1605 PP	Lens B	98	49	PVP K90 (1.25%)
Exxon 1605 PP	Lens B	20	6	PVP K90 (1.0%)
Exxon 1605 PP	Lens B	20	10	PVP K90 (.75%)

Exxon 1605 PP	Lens B	20	17	PVP K90 (.5%)
Exxon 1605 PP	Lens C	248	5	PVP K90 (5.0%)
Exxon 1605 PP	Lens C	39	0	PVP K90 (10%) Blended down to 5%
Exxon 1605 PP	Lens C	135	42	PVP K90 (2.5%)
Exxon 1605 PP	Lens C	135	54	PVP K90 (1.25%)
Exxon 1605 PP	Lens C	70	42	PVP K90 (1.0%)
Exxon 1605 PP	Lens C	70	50	PVP K90 (.75%)
Exxon 1605 PP	Lens C	70	60	PVP K90 (.5%)
Exxon 1605 PP	Lens B	15	14	Nucrel 535 - 10.5% acid comonomer (2%)
Exxon 1605 PP	Lens B	15	15	Nucrel 925 - 15% acid comonomer (3%)
Exxon 1605 PP	Lens C	15	14	Nucrel 535 - 10.5% acid comonomer (2%)
Exxon 1605 PP	Lens C	15	14	Nucrel 925 - 15% acid comonomer (3%)
Exxon 1605 PP	Lens B	15	15	2% XNAP with Pluronic
Exxon 1605 PP	Lens C	15	14	2% XNAP with Pluronic
Exxon 1605 PP	Lens B	15	15	Pluronic 1%
Exxon 1605 PP	Lens C	15	15	Pluronic 1%
Exxon 1605 PP	Lens B	15	11	1% Tetronic
Exxon 1605 PP	Lens C	15	15	1% Tetronic
Exxon 1605 PP	Lens B	15	15	1% Flura
Exxon 1605 PP	Lens C	15	15	1% Flura
Exxon 1605 PP	Lens B	30	23	2% Pluronic
Exxon 1605 PP	Lens C	30	16	2% Pluronic
Exxon 1605 PP	Lens C	77	0	PVP K90 (5%) + Epolene E43 (5%)
Exxon 1605 PP	Lens B	50	0	PVP K90 (5%) + Epolene E43 (5%)
Exxon 1605 PP	Lens C	62	0	PVP K90 (5%) + Epolene E43 (1.5%)
Exxon 1605 PP	Lens B	50	0	PVP K90 (5%) + Epolene E43 (1.5%)
Exxon 1605 PP	Lens C	65	0	PVP K90 (2.5%) + Epolene E43 (1.25%)
Exxon 1605 PP	Lens B	50	0	PVP K90 (2.5%) + Epolene E43 (1.25%)
Exxon 1605 PP	Lens C	115	10	PVP K90 (1%) + Epolene E43 (1%)
Exxon 1605 PP	Lens B	100	11	PVP K90 (1%) + Epolene E43 (1%)
Exxon 1605 PP	Lens C	30	0	PVP K29/31 (5%)
Exxon 1605 PP	Lens C	30	0	PVP K60 (5%)
Exxon 1605 PP	Lens B	50	0	PVP K90 (1%) + Rough Bowl (UP)
Exxon 1605 PP	Lens C	50	0	PVP K90 (1%) + Rough Bowl (UP)
Exxon 1605 PP	Lens B	170	0	Epolene E43 (1%) + Rough Bowl
Exxon 1605 PP	Lens C	200	0	Epolene E43 (1%) + Rough Bowl

What is claimed is

1. A package for storing medical devices in a solution comprising a molded base wherein the molded base comprises an additive, provided that the medical device is not a contact lens consisting of acqualfilcon A coated with polyHema.

2. The package of claim 1 wherein the additive is selected from the group consisting of succinic acid, glycerol monostearate, PVP, and PVP/maleic anhydride.

3. The package of claim 1 wherein the additive is glycerol monostearate.

4. The package of claim 3 wherein glycerol monostearate is present at a concentration of greater than about 0.5 weight percent to about 5 weight percent.

5. The package of claim 3 wherein glycerol monostearate is present at a concentration of about 2 percent.

6. The package of claim 1 wherein the additive is PVP KD90.

7. The package of claim 6 wherein the PVP concentration is about 1% to about 5%.

8. The package of claim 6 wherein the PVP concentration is about 1.0%.

9. The package of claim 1 wherein the additive is PVP KD90/maleic anhydride.

10. The package of claim 9 wherein the PVP KD90/maleic anhydride concentration is about 1/1% to about 5/5%.

11. The package of claim 1 wherein the medical device is a contact lens which comprises balafilcon A, lotrafilcon A, galyfilcon, senofilcon, or lenses disclosed in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002.

12. The package of claim 11 wherein the contact lens comprises Simma 2 and mPDMS.

13. The package of claim11 wherein the contact lens comprises Simma 2

14. The package of claim 1 wherein the molded base comprises polypropylene.

15. The package of claim 1 further comprising a cavity formed in said molded base wherein said cavity comprises an inner surface, wherein said inner surface has an average roughness of about 0.5 μm to about 20 μm.

16. The package of claim 15 wherein the inner surface has an average roughness of about 1.8 μm to about 4.5 μm.

17. The package of claim 15 wherein the inner surface has an average roughness of about 1.9 μm to about 2.1 μm

18. The package of claim 15 wherein the inner surface has an average roughness of about 0.5 μm to about 0.8 μm.

19. The package of claim 1 further comprising a cavity formed in said molded base wherein said cavity comprises an inner surface, wherein said inner surface has an average roughness of about 0.5 μm to about 20 μm and the additive is glycerol monostearate or PVP.

20. The package of claim 19 wherein the average roughness of the inner surface is about 0.5 μm to about 0.8 μm and the concentration of PVP is about 1%.

21. The package of claim 19 wherein the inner surface has an average roughness of about 1.9 μm to about 2.1 μm and the concentration of PVP is about 1%.

22. The package of claim 1 further comprising a cavity formed in said molded base wherein said cavity comprises an inner surface, wherein said inner surface has an average roughness of about 0.5 μm to about 20 μm and the additive is maleic anhydride or PVP/maleic anhydride.

23. The package of claim 22 wherein the average roughness of the inner surface is about 0.5 μm to about 0.8 μm and the concentration of PVP/maleic anhydride is about 1%.

24. The package of claim 22 wherein the inner surface has an average roughness of about 1.9 μm to about 2.1 μm and the concentration of PVP/maleic anhydride is about 1%.

25. The package of claim 22 wherein the average roughness of the inner surface is about 0.5 μm to about 0.8 μm and the concentration of maleic anhydride is about 1%.

26. The package of claim 22 wherein the inner surface has an average roughness of about 1.9 μm to about 2.1 μm and the concentration of maleic anhydride is about 1%.

27. A method of reducing the adherence of a medical device to its packaging, comprising storing said medical device in a solution in a package comprising a molded base wherein said molded base comprises an additive,

provided that the medical device is not a contact lens consisting of acqualfilcon A coated with polyHema.

28. The method of claim 27 wherein additive is selected from the group consisting of succinic acid, glycerol monostearate, and PVP.

29. The method of claim 27 wherein the additive is glycerol monostearate.

30. The method of claim 27 wherein glycerol monostearate is present at a concentration of greater than about 0.25 weight percent to about 5 weight percent.

31. The method of claim 27 wherein glycerol monostearate is present at a concentration of about 2 percent.

32. The method of claim 27 wherein the additive is PVP KD90.

33. The method of claim 27 wherein the PVP is present at about 1% to about 5%.

34. The method of claim 27 wherein the contact lens comprises balafilcon A, lotrafilcon A, or lenses disclosed in U.S. Pat. App. No. 60/318,536, entitled Biomedical Devices Containing Internal wetting Agents," filed on September 10, 2001 and its non-provisional counterpart of the same title, filed on September 6, 2002.

35. The method of claim 27 wherein the contact lens comprises Simma 2

36. The method of claim 27 wherein the molded base comprises polypropylene.

37. The method of claim 27 further comprising a cavity formed in said molded base wherein said cavity comprises an inner surface, wherein said

inner surface has an average roughness of about 0.5 μm to about 20 μm and the additive is glycerol monostearate or PVP.

38. The method of claim 37 wherein the average roughness of the inner surface is about 0.5 μm to about 0.8 μm and the concentration of PVP is about 1%.

39. The method of claim 37 wherein the inner surface has an average roughness of about 1.9 μm to about 2.1 μm and the concentration of PVP is about 1%.

40. The method of claim 27 further comprising a cavity formed in said molded base wherein said cavity comprises an inner surface, wherein said inner surface has an average roughness of about 0.5 μm to about 20 μm and the additive is maleic anhydride or PVP/maleic anhydride.

41. The method of claim 40 wherein the average roughness of the inner surface is about 0.5 μm to about 0.8 μm and the concentration of PVP/maleic anhydride is about 1%.

42. The method of claim 40 wherein the inner surface has an average roughness of about 1.9 μm to about 2.1 μm and the concentration of PVP/maleic anhydride is about 1%.

43. The method of claim 40 wherein the average roughness of the inner surface is about 0.5 μm to about 0.8 μm and the concentration of maleic anhydride is about 1%.

44. The method of claim 40 wherein the inner surface has an average roughness of about 1.9 μm to about 2.1 μm and the concentration of maleic anhydride is about 1%.

45. A method of hydrating a contact lens comprising, consisting essentially of, or consisting of hydrating said lens in a molded base wherein said molded base comprises an additive.

46. The method of claim 45 wherein the additive is selected from the group consisting of succinic acid, glycerol monostearate, PVP, and PVP/maleic anhydride.

47. The method of claim 46 wherein the additives are present at a concentration of greater than about 0.25 weight percent to about 5 weight percent.

48. The method of claim 45 wherein the molded base further comprises a cavity formed in said molded base wherein said cavity comprises an inner surface, wherein said inner surface has an average roughness of about 0.5 μm to about 20 μm and the additive is maleic anhydride or PVP/maleic anhydride.

FIG. 1

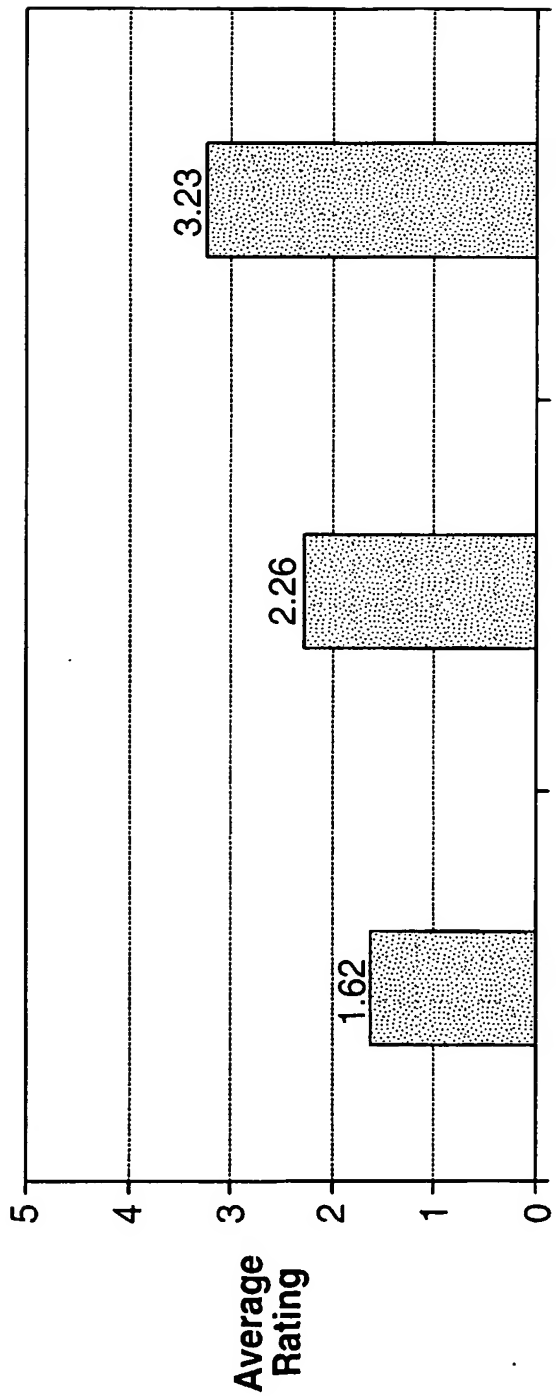


FIG. 2

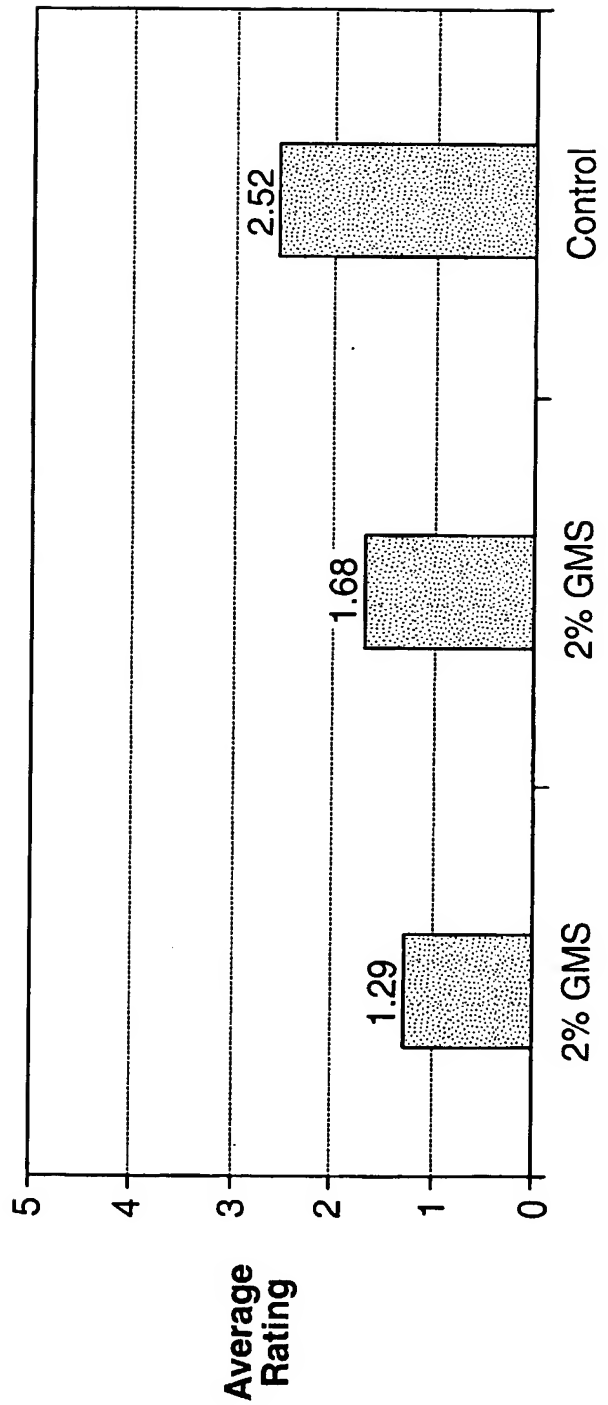
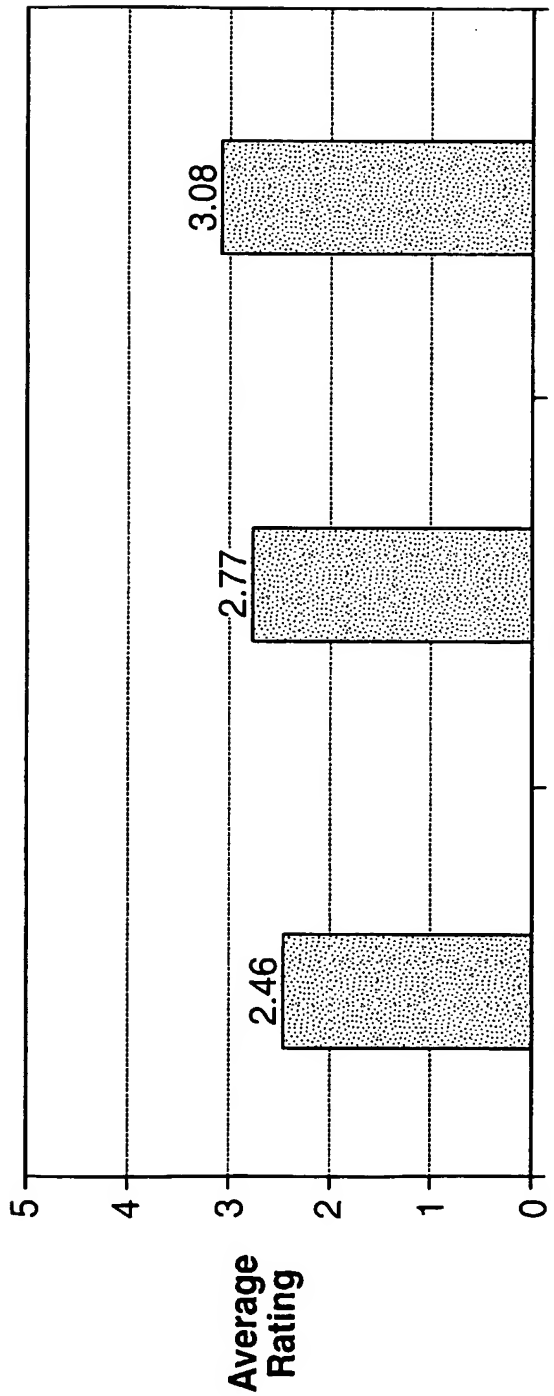


FIG. 3



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 July 2004 (22.07.2004)

PCT

(10) International Publication Number
WO 2004/060099 A3

(51) International Patent Classification[7]: A61L 12/08, A45C 11/00, 11/04, B65B 25/00

(21) International Application Number: PCT/US2003/039017

(22) International Filing Date: 9 December 2003 (09.12.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/436,109 23 December 2002 (23.12.2002) US

(71) Applicant: JOHNSON & JOHNSON VISION CARE INC. [US/US]; 7500 Centurion Parkway, Jacksonville, FL 32256 (US).

(72) Inventors: PECK, James; 13587 Osprey Point Drive, Jacksonville, FL 32224 (US). DUBEY, Dharmesh; 9087 Starpass Drive, Jacksonville, FL 32256 (US). TOKARSKI, Michael; 500 N. Lakewood Run, Ponte Vedra Beach, FL 32082 (US). ZHANG, Qiang; 27 LaCosta Drive, Annandale, NJ 08801 (US). LI, Yufu; 11 Hughes Road, Bridgewater, NJ 08807 (US). ARNOLD, Steven; 26 Hideaway Lane, Sparta, NJ 07871 (US).

(74) Agents: JOHNSON, Philip S, et al.; Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, NJ 08933 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

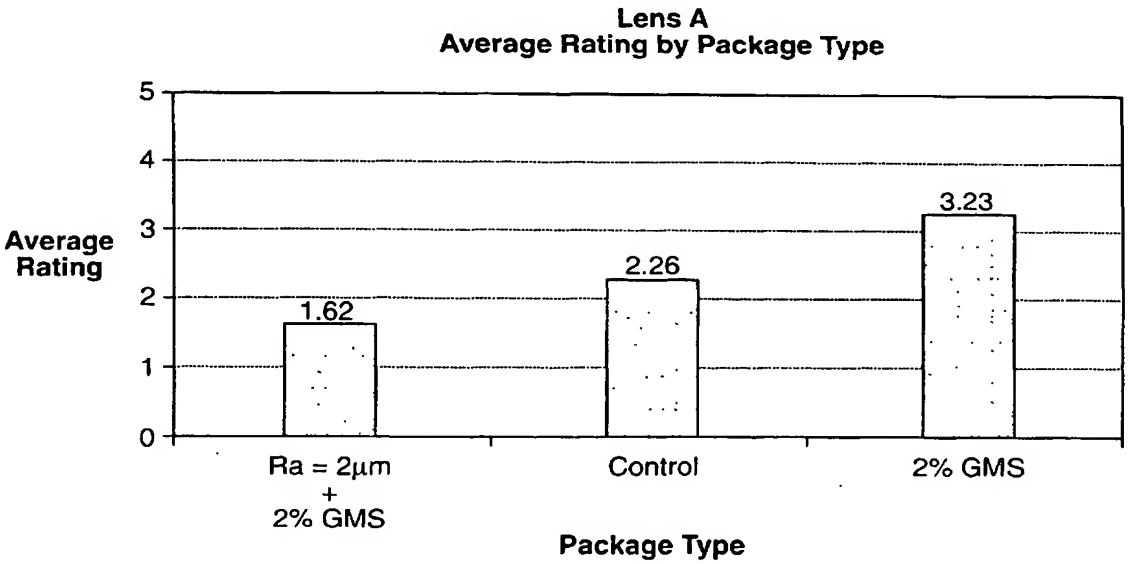
(84) Designated States *(regional)*: ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
2 September 2004

[Continued on next page]

(54) Title: MEDICAL DEVICE PACKAGES CONTAINING ADDITIVES



(57) Abstract: A package comprising a moulded base having an additive that presents the adhesion of a medical device enclosed in the package.

WO 2004/060099 A3

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/39017

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61L12/08 A45C11/00 A45C11/04 B65B25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61L A45C B65B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/069896 A1 (PANKOW MARK L) 13 June 2002 (2002-06-13) paragraphs '0016!, '0072!	1,27
X	EP 0 367 513 A (BRITISH TECH GROUP) 9 May 1990 (1990-05-09) column 5, lines 17-21 column 6, lines 9-11 column 7, line 48 - column 8, line 11	45
X	GB 2 078 760 A (METAL BOX CO LTD) 13 January 1982 (1982-01-13) page 1, lines 3-17 page 1, lines 43-45	1-5, 14-19, 27-31, 36,37

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 July 2004	23.07.04

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jochheim, J

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

	ial Application No
	PCT/US 03/39017

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 033 326 A (JOHNSON & JOHNSON VISION CARE) 6 September 2000 (2000-09-06) paragraphs '0013!, '0018! - '0021!, '0041!; claims 1,16,17	1,27
A	US 4 100 309 A (MICKLUS MICHAEL J ET AL) 11 July 1978 (1978-07-11) column 1, lines 8-48	1,2,6, 15-18, 20,27, 28,33,37
A	DATABASE WPI Section Ch, Week 197737 Derwent Publications Ltd., London, GB; Class A96, AN 1977-65891Y XP002287714 & JP 52 093398 A (TOA IYO DENSHI KK) 5 August 1977 (1977-08-05) abstract	1,2,6-8, 14
A	US 4 981 657 A (RYDER FRANCIS E) 1 January 1991 (1991-01-01) column 2, lines 7-14; claim 1	1,27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/39017

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 2 (part), 27, 28 (part)

A package for storing medical devices in a solution comprising a molded base wherein the molded base comprises a succinic acid additive.
A method of reducing the adherence of a medical device to its packaging, comprising storing said medical device in a solution in a package comprising a molded base and a succinic acid additive.

---

2. claims: 1, 2 (part), 27, 28 (part)

A package for storing medical devices in a solution comprising a molded base wherein the molded base comprises a glycerol monostearate additive.
A method of reducing the adherence of a medical device to its packaging, comprising storing said medical device in a solution in a package comprising a molded base and a glycerol monostearate additive.

---

3. claims: 1, 2 (part), 27, 28 (part)

A package for storing medical devices in a solution comprising a molded base wherein the molded base comprises a PVP additive.
A method of reducing the adherence of a medical device to its packaging, comprising storing said medical device in a solution in a package comprising a molded base and a PVP additive.

---

4. claims: 1, 2 (part), 27, 28 (part)

A package for storing medical devices in a solution comprising a molded base wherein the molded base comprises a PVP/maleic anhydride additive.
A method of reducing the adherence of a medical device to its packaging, comprising storing said medical device in a solution in a package comprising a molded base and a PVP/maleic anhydride additive.

---

5. claims: 45, 46 (part)

A method of hydrating a contact lens comprising, consistin essentially of, or consisting of hydrating said lens in a molded base wherein said molded base comprises a succinic acid additive.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

6. claims: 45, 46 (part)

A method of hydrating a contact lens comprising, consistin essentially of, or consisting of hydrating said lens in a molded base wherein said molded base comprises a glycerol monostearate additive.

---

7. claims: 45, 46 (part)

A method of hydrating a contact lens comprising, consistin essentially of, or consisting of hydrating said lens in a molded base wherein said molded base comprises a PVP additive.

---

8. claims: 45, 46 (part)

A method of hydrating a contact lens comprising, consistin essentially of, or consisting of hydrating said lens in a molded base wherein said molded base comprises a PVP/maleic anhydride additive.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In tional Application No
PCT/US 03/39017

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002069896 A1	13-06-2002	US 6280530 B1	28-08-2001
		AU 3115901 A	07-08-2001
		CA 2398245 A1	02-08-2001
		EP 1259333 A1	27-11-2002
		JP 2003521003 T	08-07-2003
		WO 0154834 A1	02-08-2001
EP 0367513 A	09-05-1990	AT 124649 T	15-07-1995
		AT 157301 T	15-09-1997
		AT 147323 T	15-01-1997
		AU 632071 B2	17-12-1992
		AU 4431489 A	10-05-1990
		CA 2001948 A1	02-05-1990
		CN 1043463 A ,B	04-07-1990
		CN 1065342 A ,B	14-10-1992
		CN 1122277 A ,B	15-05-1996
		DE 68923345 D1	10-08-1995
		DE 68923345 T2	21-12-1995
		DE 68927648 D1	20-02-1997
		DE 68927648 T2	24-04-1997
		DE 68928283 D1	02-10-1997
		DE 68928283 T2	02-01-1998
		DK 543789 A	03-05-1990
		DK 200000661 A	18-04-2000
		EP 0367513 A2	09-05-1990
		EP 0561480 A2	22-09-1993
		EP 0561481 A2	22-09-1993
		ES 2076216 T3	01-11-1995
		ES 2108208 T3	16-12-1997
		ES 2096846 T3	16-03-1997
		GB 2226272 A ,B	27-06-1990
		GB 2237240 A ,B	01-05-1991
		GB 2237241 A ,B	01-05-1991
		GR 3017372 T3	31-12-1995
		GR 3022419 T3	30-04-1997
		GR 3025140 T3	27-02-1998
		HK 16794 A	11-03-1994
		HK 16994 A	11-03-1994
		HK 74193 A	06-08-1993
		HK 133197 A	24-10-1997
		HK 1001228 A1	05-06-1998
		HK 1001251 A1	05-06-1998
		IN 175890 A1	21-10-1995
		IN 174309 A1	05-11-1994
		JP 1923651 C	25-04-1995
		JP 2172712 A	04-07-1990
		JP 6051305 B	06-07-1994
		SU 1838134 A3	30-08-1993
		RU 2044653 C1	27-09-1995
		US 5573108 A	12-11-1996
		US 5578332 A	26-11-1996
		US 5143660 A	01-09-1992
GB 2078760 A	13-01-1982	CA 1251746 A1	28-03-1989
		DE 3124196 A1	15-04-1982
		FR 2484955 A1	24-12-1981
		IN 153966 A1	08-09-1984
		IT 1137092 B	03-09-1986

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/39017

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
GB 2078760	A		ZA	8104025 A	30-06-1982
EP 1033326	A	06-09-2000	AU	765985 B2	09-10-2003
			AU	1954700 A	07-09-2000
			BR	0001742 A	10-10-2000
			CA	2299691 A1	01-09-2000
			CN	1281687 A	31-01-2001
			EP	1033326 A1	06-09-2000
			JP	2000255642 A	19-09-2000
			SG	85161 A1	19-12-2001
			TW	514585 B	21-12-2002
			US	2002197478 A1	26-12-2002
US 4100309	A	11-07-1978	AR	219763 A1	15-09-1980
			AU	512679 B2	23-10-1980
			AU	3856878 A	05-06-1980
			BE	869588 A1	01-12-1978
			BR	7805057 A	17-04-1979
			CA	1109344 A1	22-09-1981
			CH	639675 A5	30-11-1983
			CH	634590 A5	15-02-1983
			DE	2828617 A1	01-03-1979
			FR	2399879 A1	09-03-1979
			GB	1600963 A	21-10-1981
			IT	1109430 B	16-12-1985
			JP	1246290 C	25-12-1984
			JP	54029343 A	05-03-1979
			JP	59019582 B	07-05-1984
			MX	151865 A	11-04-1985
			NL	7808290 A ,B,	12-02-1979
			SE	441064 B	09-09-1985
			SE	7808442 A	10-02-1979
			US	4119094 A	10-10-1978
JP 52093398	A	05-08-1977	NONE		
US 4981657	A	01-01-1991	NONE		